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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

OCT 29 2004

WARNING LETTER

FEDERAL EXPRESS

Ramzi F. Abulhaj
President, VitalCare Group, Inc.
c/o VitalCare Jianda Medical Apparatus
and Instruments, Ltd.
8935 NW 27th Street
Miami, Florida 33172

Dear Mr. Abulhaj:

During an inspection of your manufacturing facility located in Shanghai, P.R. China, on May 17, 2004, through May 20, 2004, our investigator determined that your facility is a manufacturer for Class I sterile devices, including, but not limited to, the following: a urethral catheterization tray, catheter kit, Foley insertion tray, irrigation tray, tracheostomy care kit, and irrigation syringe bulb control. These products are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(h)).

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. Significant violations include, but are not limited to, the following:

1. Failure to document validation results for [redacted] sterilization procedures, as required by 21 CFR 820.75(a).

   For example, during the inspection, our investigator requested that your firm provide the validation results for the sterilization work instructions used in accordance with your [redacted] sterilization protocol, [redacted] These validation results were not available for our review during the inspection.

2. Failure to establish and maintain corrective and preventive action procedures to analyze work operations and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems, as required by 21 CFR 820.100(a)(1).

For example, in-process nonconformities, i.e., shutdown of the [redacted] machine [redacted], were not evaluated by the Corrective/Preventive Action (CAPA) Procedure, [redacted] for quality problems. Also, nonconformities from receiving acceptance activities, i.e., acceptance of [redacted] were not evaluated by the CAPA procedure.

3. Failure to establish and maintain procedures for acceptance of incoming product, as required by 21 CFR 820.80(b).

   For example, your firm did not establish and maintain procedures for acceptance of [redacted] does not require that inspection and acceptance of [redacted] be documented.

4. Failure to establish and maintain in-process acceptance procedures to ensure that specified requirements for in-process product are met, as required by 21 CFR 820.80(c).

   For example, during our inspection, our investigator observed that your manufacturing facility did not follow the [redacted] which requires verification inspection of first-piece samples whenever the [redacted] machine is started following maintenance or shutdown after it was stopped and restarted to replace a leaking pressure valve.

5. Failure to document calibration records, as required by 21 CFR 820.72(b)(2).

   For example, you failed to document calibration of the sterilization chamber's humidity gauge and temperature sensor during our inspection.

6. Management reviews are not conducted at defined intervals and with a sufficient frequency according to established procedures to ensure that the quality system satisfies regulatory requirements and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c).

   For example, the [redacted] states that management reviews are to be held bi-annually. However, our investigator confirmed that management reviews are only held once per year.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form

FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations and take prompt actions to correct the violations and to bring your products into compliance.

We received a response from Michael McAvenia, Director of Quality Assurance, dated June 24, 2004, concerning our investigator's observations noted on the FDA 483. We have reviewed your response and have concluded that it is inadequate for the following reasons:

1. The [redacted] validation results requested during our inspection were not submitted with your response. Please submit the validation results and the revised [redacted] sterilization validation protocol and results that were in progress during the inspection for our review.

2. The revised CAPA procedure that you submitted with your response is not adequate because it does not reflect the updated revision number, the signature of the approving individual(s), the approval date, and when the change becomes effective, as required by the document control requirements of 21 CFR 820.40(b). Please submit a revised CAPA procedure that addresses the document controls requirements for our review.

3. The revised [redacted] procedure that you submitted with your response is not adequate because there are no specific instructions for the acceptance activities, i.e., verification and documentation of expiration date, which will be performed for the incoming [redacted]. Also, the revised [redacted] does not reflect the updated revision number, the signature of the approving individual(s), the approval date, and when the change becomes effective, as required by the document control requirements of 21 CFR 820.40(b). Please submit a revised procedure that addresses the acceptance activities for the incoming [redacted] and addresses the document controls requirements for our review.

4. The humidity gauge and temperature sensor calibration records that you provided with your response are not adequate because the calibration dates do not make clear when the equipment was calibrated and the records do not specify the next calibration date. Please submit annotated calibration records that specify the calibration date and the next required calibration date for our review.

5. The Training Certifications for [redacted] which you provided in your June 24, 2004, response, are not

adequate because these records are not signed by the employees specifying the year of the training. Also, the titles of the employees taking training are not specified to ensure that all personnel with quality system activity responsibilities have been trained. Please submit revised Training Certifications that specify the employees' titles and which are dated with the year of training for our review.

Please submit the following information in addition to the above:

1. Please provide labeling, packaging, or promotional materials for the pediatric and adult single suction catheters with graduations that are listed on the Bill of Material for the VitalCare Suction Catheter Kit that was collected by our investigator during the inspection. This information is needed for our review in making an appropriate device classification determination.

2. As requested during the May 20, 2004, final discussion with management, please provide confirmation of the disposition of the [redacted] that was seeded with [redacted] and was held under quarantine at the close of our inspection.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, which may include detaining your devices without physical examination upon entry into the United States until the corrections are completed. Section 801(a) of the Act (21 U.S.C. § 381(a)).

Please notify this office in writing within fifteen (15) working days from the date you receive this letter, of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this letter as well. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement B, Orthopedic, Physical Medicine, and Anesthesiology Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850 USA, to the attention of William MacFarland.

If you need help in understanding the contents of this letter, please contact Emil P. Wang at the above address or at (240) 276-0120 or FAX (240) 276-0129.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health